REMARKS

I. Status of Claims

Upon entry of the Amendment, which is respectfully requested, claims 1 and 3-8 will be pending in the application.

Claim 1 is amended to correct antecedent basis. Claim 3 is amended to correct minor typographic errors, and to correct the recitation of a Markush group in the claim language. Claims 4 and 6 are amended to delete the word "preferred". Claim 7 is amended to correct a minor typographic error.

Claims 9-22 are canceled without prejudice or disclaimer.

No new matter is added. Accordingly, entry of the Amendment is respectfully requested.

II. Response to Objection to Claim 3

The Examiner has objected to claim 3 because of a minor typographical error.

Applicants respectfully submit that the objection to claim 3 is overcome in view of the amendment to claim 3.

III. Response to Claim Rejections Under 35 U.S.C. § 112

Claims 4 and 6 are rejected under 35 U.S.C. § 112, as allegedly being indefinite. Specifically, the Examiner states that the recitation of the word "preferred" in claims 4 and 6, renders the claims indefinite, as Applicants' intended definition of the word "preferred" is unclear.

Applicants respectfully submit that the rejection is overcome by amending claims 4 and 6 to delete the word "preferred".

IV. Response to Claim Rejection Under 35 U.S.C. § 102

Claims 1, 3 and 5-8 rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sharma et al. (Pharmaceutical Research, Vol. 18, pp. 1405-1410).

Applicants respectfully traverse.

Claim 1 recites that the ratio of the anti-tuberculosis drugs is 1:2 to 2:1. In contrast, Sharma et al. discloses a ratio of isoniazid to rifampicin of 1:3. The ratio 1:3, as disclosed in Sharma et al., falls outside the presently claimed range of 1:2 to 2:1. At page 4 of the Office Action, the Examiner states that the range as presently claimed is disclosed in Sharma et al., because in Table 1 at page 1407 of Sharma et al., the ratio of isonazid to rifampicin is from 3:2 to 1:1. However, the presently claimed drug ratio refers to the initial amount of drug present in the microcapsule, and Table 1 of Sharma et al. lists the initial amount of drug administered as being 4.9:15, which is equivalent to 1:3.

Additionally, in the section entitled "Formulation" at page 1406 of Sharma et al., it is disclosed that the microcapsule contains one part drug to three parts of PLA, i.e., the drug to polymer ratio is 1:3. This further distinguishes the presently claimed microcapsules over those of Sharma et al., as claim 1 recites that the instant microcapsules have a drug to polymer ratio in the range 1:2 to 2:1.

In view of the above, Applicants respectfully submit that Sharma et al. do not teach or suggest each and every element of present claim 1. Therefore, claim 1 is patentable over Sharma et al. Further, claims 3 and 5-8 are also patentable, at least by virtue of their dependence from claim 1.

Therefore, reconsideration and withdrawal of the § 102 rejection of claims 1, 3 and 5-8 based on Sharma et al. are respectfully requested.

V. Response to Claim Rejections Under 35 U.S.C. § 103

A. Claims 1 and 3-8 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Takada et al. (U.S. Patent No. 6,117,455) in view of Baker et al. (U.S. Patent No. 5,399,558).

Applicants respectfully traverse.

Takeda et al., at column 13, lines 41-56, states that the microcapsules may be processed into solid, semi-solid or liquid nasal preparations by conventional methods. It is further stated that the solid intranasal preparations can be prepared as powdery compositions from the microcapsules themselves, or together with additives. The working Examples of Takeda et al. disclose the use of powdery microcapsules, but do not specifically disclose an administration method for the microcapsules.

At column 1, lines 53-55 of Takada et al., it is disclosed that the invention therein provides a microcapsule comprising a physiologically active substance in the form of microparticles and a polymer. Furthermore, at column 7, lines 52-55, it is disclosed that the physiologically active substance is in the form of microparticles, ranging from about 1 nm to 10 µm and more preferably between 1 nm and 1 µm, and at column 12, lines 63-65 it is disclosed that the average diameter of the micapsules is preferably between 0.5 to 400 µm and more preferably between 2 to 200 µm.

In view of the above, it is apparent that the "microparticle" of Takeda is drug only, while the "microcapsule" of Takeda contains a polymer and a drug "microparticle. In contrast, in the presently claimed invention, the "microparticle" contains both the drug and the polymer. As Baker et al. does not disclose microparticles, Baker et al. does not cure the above deficiency of Takada et al. with respect to the presently claimed invention.

In view of the above, claims 1 and 3-8 are patentable over the combination of Takeda et al. and Baker et al. Therefore, reconsideration and withdrawal of the § 103 rejection are respectfully requested.

B. Claims 1 and 3-8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Barrow et al. (U.S. Patent No. 6,264,991).

Applicants respectfully traverse.

The working Examples of Barrow et al., disclose the use of rifampicin alone, and not in combination with any other drug. Therefore, there is no motivation to combine two anti-tubercular drugs based on the teachings of Barrow et al.

In contrast, present claim 1 recites, in part, a biodegradable inhalable microparticle composition comprising two anti-tubercular drugs. Furthermore, in the working Examples of the present application, Groups 1 and 2 correspond to the administration of a combination of two anti-tubercular drugs (isoniazid and rifabutin), whereas group 5 corresponds to the administration of only rifabutin. Figs. 1 and 2 of the present specification show the results of treatment with the above drug compositions after three and four weeks, respectively. In Figs. 1 and 2, Groups 1 and 2 are identified as "Inhalation" and "Oral 10 mg/kg (INH + RB pure drugs)+Inhalation", respectively, and Group 5 is identified as "Oral 20 mg/kg RB pure drug". Both Figs. 1 and 2 show that the administration of the combination of isoniazid and rifabutin results in faster clearance of tubercular bacilli from the lungs than administration of rifabutin alone. Thus, the combination of isoniazid and rifabutin has improved efficacy in the treatment of tuberculosis, as compared to treatment with rifabutin alone, according to the results of Barrow et al.

Accordingly, claims 1 and 3-8 are patentable over Barrow et al., and reconsideration and withdrawal of the § 103 rejection based on Barrow et al. are respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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